

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant :	Andrew David Morley et al.	Art Unit :	1626
Patent No. :	7,553,868	Examiner :	Rebecca L. Anderson
Issue Date :	June 30, 2009	Conf. No. :	8677
Serial No. :	10/542,044		
Filed :	July 13, 2005		
Title :	THIOPHENE CARBOXAMIDES AS INHIBITORS OF THE ENZYME IKK-2		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)

Patentee hereby requests reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent. Reconsideration of the final PTA calculation to increase total PTA from 88 to 174 days, is respectfully requested.

REMARKS

(1) Measuring Overlap of “A Delay” and “B Delay”

“A Delays” are defined as delays by the U.S. Patent and Trademark Office (PTO) under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO response. “B Delays” are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than three year application pendency. To the extent that the periods of delay overlap, the period of any term adjustment shall not exceed the actual number of days the issuance of the patent was delayed. 35 U.S.C. § 154(b)(2)(A). As outlined in Wyeth et al. v. Jon W. Dudas (580 F. Supp. 2d 138; 88 USPQ 2d 1538), the only way that these periods of time can “overlap” is if they occur on the same day. If an “A delay” occurs on one calendar day and a “B delay” occurs on another calendar day, they do not overlap and 35 U.S.C. § 154(b)(2)(A) does not limit the extension to one day. Id.

The PTA for the instant patent, as currently calculated and shown on the face of the patent, apparently relies on the premise that the application was delayed under 35 U.S.C. § 154(b)(1)(B) *before* the initial three-year period expired. The Wyeth v. Dudas court

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determined that this construction cannot be squared with the language of 35 U.S.C. § 154(b)(1)(B), which applies “if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years.” “B delay” begins only after the PTO has failed to issue a patent within three years, not before. Id.

(2) Measuring “B Delay” for a National Stage Filing under 35 U.S.C. § 371

In addition to and independent of the “overlap” issue addressed above, Patentee respectfully submits that the Office did not apply the proper standard for determining the period of “B Delay” under 35 U.S.C. § 154(b)(1)(B). It is Patentee’s understanding that for purposes of calculating “B Delay,” the Office measured application pendency as beginning on July 13, 2005, the date on which the application fulfilled the requirements of 35 U.S.C. § 371.

The term of a patent shall, under certain circumstances, be extended if the Office fails to issue a patent within three years after the “actual filing date” of the application.

(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States ... the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued. 35 U.S.C. § 154(b)(1)(B). (emphasis added)

37 C.F.R. § 1.702(b) explains the meaning of the term “actual filing date” as used in 35 U.S.C. § 154(b)(1)(B). As detailed below, PTO delay for a national stage application begins if the Office fails to issue a patent within three years after the date the national stage “commenced under 35 U.S.C. 371(b) or (f).”¹

(b) *Failure to issue a patent within three years of the actual filing date of the application.* Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national

¹ Consistent with 37 C.F.R. § 1.702(b), MPEP § 2730 states that “[i]n the case of an international application, the phrase ‘actual filing date of the application in the United States’ [as used in 35 U.S.C. § 154(b)(1)(B)] means the date the national stage commenced under 35 U.S.C. 371(b) or (f).”

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stage commenced under 35 U.S.C. 371(b) or (f) in an international application, but not including... 37 C.F.R. § 1.702(b). (emphasis added)

35 U.S.C. §§ 371(b) and (f) refer to the time when a national stage application “commences.”

(b) Subject to subsection (f) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22 (1) or (2), or under article 39 (1)(a) of the treaty. 35 U.S.C. § 371(b). (emphasis added)

(f) At the express request of the applicant, the national stage of processing may be commenced at any time at which the application is in order for such purpose and the applicable requirements of subsection (c) of this section have been complied with. 35 U.S.C. § 371(f).

35 U.S.C. § 371(f) relates to the situation where an applicant files an express request for early processing of an international application. In the absence of filing such a request, the U.S. national stage commences under the provisions of 35 U.S.C. § 371(b), i.e., with the expiration of the applicable time limit under article 22(1) or (2), or under article 39(1)(a) of the treaty. The term “the treaty” refers to “the Patent Cooperation Treaty done at Washington, on June 19, 1970.” See 35 U.S.C. § 351(a).

REVIEW OF PATENT TERM ADJUSTMENT CALCULATION

“A Delay”

A first PTO action was due on or before September 13, 2006 (the date that is fourteen months after July 13, 2005, the date on which the application fulfilled the requirements of 35 U.S.C. § 371). The PTO mailed the first non-final Office Action on February 9, 2007, thereby according a PTO Delay of 149 days. Patentee does not dispute the PTO’s calculation for this “A Delay” from September 14, 2006 (the day after the date that is four months after the date on which a response to Office Action was filed), to February 9, 2007. See 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1).

In view of the period of “A Delay” detailed above, the total “A Delay” for this patent should be calculated as 149 days.

"B Delay"

The present application is a national stage filing under 35 U.S.C. § 371 of international application number PCT/GB2004/000106, filed January 13, 2004, which claims the benefit of priority of Sweden application number 0300091-6, filed January 15, 2003.

The national stage for the present application "commenced" under the provisions of 35 U.S.C. § 371(f), i.e., upon express request for processing of the application and upon compliance with all the applicable requirements of 35 U.S.C. § 371(c).² As a result, the date that the national stage commenced was July 13, 2005.

The period beginning on July 14, 2008 (the day after the date that is three years after July 13, 2005, the date that the national stage commenced), and ending June 30, 2009 (the date the patent was issued), is 352 days in length.

"B Delay" may not include the number of days in the period beginning on the date on which a Request for Continued Examination was filed and ending on the date the patent was issued. In the present application, a Request for Continued Examination was filed on October 7, 2008, and the patent issued on June 30, 2009, which resulted in a period of 266 days that must be excluded from the three year delay calculation.

See 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1).

In addition, "B Delay" may not include the number of days in the period beginning on the date on which a Notice of Appeal was filed and ending on the date of mailing of a Notice of Allowance. In the present application, no Notice of Appeal was filed.

See 37 C.F.R. §§ 1.702(b)(4) and 1.703(b)(4).

In view of the periods of "B Delay" detailed above, the total "B Delay" for this patent should be calculated as 86 days (i.e., 352 days minus 266 days). The PTO calculated 0 days of delay for issuance of a patent more than three years after filing. Patentee respectfully submits that the PTO's calculation of this "B Delay" is incorrect and that the correct PTO Delay for issuance beyond three years from filing is 86 days. See 37 C.F.R. §§ 1.702(b) and 1.703(b).

² A complete request for early processing under 35 U.S.C. § 371(f) was filed with the present application.

Overlap of "A Delay" and "B Delay"

As detailed above, "A Delay" accumulated during the following period:

September 14, 2006, to February 9, 2007.

As detailed above, "B Delay" accumulated during the following period:

July 14, 2008, to October 7, 2008.

As such, the periods of "A Delay" and "B Delay" do not overlap (i.e., occur on the same calendar day).

Applicant Delay

A reply to an Office Action was due on or before September 8, 2007 (the date that is three months after June 8, 2007, the date on which the Office Action was mailed). Patentee filed a response to the Office Action on November 8, 2007, thereby according an Applicant Delay of 61 days. Patentee does not dispute the PTO's calculation for this Applicant Delay from September 9, 2007 (the day after the date that is three months after the date on which the Office Action was mailed), to November 8, 2007. See 37 C.F.R. § 1.704(b).

In view of the period of Applicant Delay detailed above, the total Applicant Delay for this patent should be calculated as 61 days.

Terminal Disclaimer

This patent is not subject to a terminal disclaimer.

Conclusion

In consideration of the events described above, Patentee believes the PTA calculation of 88 days is incorrect. As such, Patentee respectfully requests reconsideration of the PTA in the following manner:

- 1) Total PTO Delay should be calculated as 235 days (i.e., the sum of 149 days of "A Delay" and 86 days of "B Delay");
- 2) Total Applicant Delay should be calculated as 61 days; and
- 3) Total PTA should be calculated as 174 days.

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The fee of \$200 required under 37 C.F.R. § 1.18(e) is being submitted herewith. Please apply any other required charges or credits to Deposit Account No. 06-1050, referencing attorney docket number 06275-0460US1.

Respectfully submitted,

Date: August 28, 2009

/John T. Kendall/

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